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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/586,177 | 07/17/2006 | Holger Timinger | DE040018US1 | 2751 |

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P.O. BOX 3001
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| EXAMINER |
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BRUTUS, JOEL F

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| ART UNIT | PAPER NUMBER |
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3768

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| MAIL DATE | DELIVERY MODE |
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01/21/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | |
|------------------------------|--------------------------------------|--|--|
| Office Action Summary | Application No. 10/586,177 | Applicant(s) TIMINGER ET AL. | |
| | Examiner JOEL F. BRUTUS | Art Unit 3768 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 November 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/17/2009 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

3. Claims 1-10 are rejected under 35 U.S.C. 102(b) as being anticipated by over Verard et al (Pub. No.: US 2004/0097805).

Regarding claims 1 and 10, Verard et al teach a navigation system 10 including a catheter 52 carrying single or multiple localization sensors, a sensor interface, a user interface, a controller, and a visual display [see 0055-0059] that anticipates the claimed invention. Verard et al teach the location of a catheter advanced within an internal space within the human body, for example within the cardiovascular structures, to be

Art Unit: 3768

identified in two, three or four dimensions in real time [see 0015]. Digitized signals are provided via a data bus to a control system or controller (use herein as data processing device, emphasis added), embodied as a computer [see 0022].

Verard et al teach a 3D heart model [see 0095-0097]; the navigation system 10 will automatically locate the reference points by monitoring the electrode and pressure sensors and this results in a visualization of the catheter 52 as it is moved through the heart model [see 0095]. Once the 3-D heart model placement is established, a mapping function can begin or a lead implant site chosen. The 3-D heart model will be scaled and rotated only within physiological bounds. Reference points outside of these bounds will generate an alert and require the physician to resolve the discrepancy [see 0095]; possible reference points (use as interpolation nodes, emphasis added) include the superior vena cava (SVC) to right atria transition, the tricuspid valve, and the left ventricular apex [see 0095].

The controller estimates the optimized site and superimposes an icon representing the location of the optimized site and an icon representing the instrument based on the sensed physiological parameter and the position of the instrument [see 0026]. This teaching of Verard et al implies the calculation of movement compensated location (emphasis added). The display displays the icon of the estimated optimized site and the icon representing the instrument in the patient [see 0026].

Verard et al teach compensate for the effects of respiration and the beating heart that can normally complicate mapping or diagnostic data [see 0015]. Tracking catheter displacement with position sensors [see 0134].

Regarding claim 2, all other limitations are taught as set forth by the above teaching.

Verard et al teach the invention allows a two, three, or four-dimensional reconstruction of the catheter body in real time [see 0017]. Visualization of the shape and position of a distal portion of the catheter makes the advancement of the catheter to a desired position more intuitive to the user [see 0017].

Once the multiple landmarks or reference points are identified in the heart, a 3-D heart model or atlas heart model is superimposed over the fluoroscopic images or modeled as a 3-D volume view by registering or translating the 3-D heart model in relation to the landmarks collected at block 148. This fusion occurs at block 150, which translates, rotates and scales the 3-D heart model, based upon the collected landmarks to provide a patient specific heart model that can be used for various procedures [see 0097].

Regarding claim 3, all other limitations are taught as set forth by the above teaching.

Verard et al teach curve fitting algorithm [see 0017, 0109].

Regarding claim 4, all other limitations are taught as set forth by the above teaching.

Art Unit: 3768

Verard et al teach the navigation system 10 may include an imaging device 12 that is used to acquire pre-operative or real-time images of a patient 14; the imaging device 12 is a fluoroscopic x-ray imaging device [see 0057] and generate a series of two and three dimensional images to be stored [see 0059].

Regarding claims 5-6, all other limitations are taught as set forth by the above teaching.

Verard et al teach locating before moving it throughout the volume [see 0017]; measured location of interpolations nodes of the body volume [see 0081]; possible reference points (use as interpolation nodes, emphasis added) include the superior vena cava (SVC) to right atria transition, the tricuspid valve, and the left ventricular apex [see 0095].

Regarding claim 7, all other limitations are taught as set forth by the above teaching.

Verard et al teach pre-operative images (static images, Emphasis added) stored within the controller/computer is designed to determine estimated location [see 0057, 0062-67, 0090].

Regarding claim 8, all other limitations are taught as set forth by the above teaching.

Art Unit: 3768

Verard et al the catheter and navigation system 10 further includes a gating device or an ECG or electrocardiogram 62, which is attached to the patient 14, via skin electrodes 64, and in communication with the coil array controller 48. Respiration and cardiac motion can cause movement of cardiac structures relative to the catheter 54, even when the catheter 54 has not been moved [see 0076-0077].

Regarding claim 9, all other limitations are taught as set forth by the above teaching.

Verard et al teach use electromagnetic fields to determine the location of the instrument or catheter [see 0071].

Response to Arguments

4. Applicant's arguments with respect to claims 1-10 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOEL F. BRUTUS whose telephone number is (571)270-3847. The examiner can normally be reached on Mon-Fri 7:30 AM to 5:00 PM (Off alternative Fri).

Art Unit: 3768

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. F. B./
Examiner, Art Unit 3768

/Long V Le/
Supervisory Patent Examiner, Art Unit 3768